

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference  P2002219C	FOR FURTHER ACTION  See Form PCT/IPEA/416	
International application No.  PCT/CN02/00579	International filing date (day/month/year)  21.Aug.2002(21.0802)	Priority date (day/month/year)
International Patent Classification (IPC) or national classification and IPC  IPC <sup>7</sup> C07D307/88, A61K31/343		
<b>Applicant</b>  ZHONGQI PHARMACEUTICAL TECHNOLOGY (SHIJIAZHUANG) CO.,LTD et al		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		

Date of submission of the demand  08.March.2004(08.03.04)	Date of completion of this report  22.April.2004(22.04.04)
Name and mailing address of the IPEA/ Patent Office of Intellectual Property Office of China 6, Xitucheng Road, Haidian District, Beijing, 100088, China	Authorized officer   Telephone No. 86-10-62085615
Facsimile No. 86-10-62019451	

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:

- international search (under Rules 12.3 and 23.1(b))
- publication of the international application (under Rule 12.4)
- international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

the international application as originally filed/furnished  
 the description:

pages	_____	as originally filed/furnished
pages *	_____	received by this Authority on _____
pages *	_____	received by this Authority on _____

the claims:

pages	_____	as originally filed/furnished
pages *	_____	as amended (together with any statement) under Article 19
pages *	_____	received by this Authority on _____
pages *	_____	received by this Authority on _____

the drawings:

pages	_____	as originally filed/furnished
pages *	_____	received by this Authority on _____
pages *	_____	received by this Authority on _____

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement:**

Novelty (N)	Claims 1-12	YES
	Claims _____	NO
Inventive step (IS)	Claims 1-12	YES
	Claims _____	NO
Industrial applicability (IA)	Claims 1-12	YES
	Claims _____	NO

**2. Citations and explanations (Rule 70.7)****1) Novelty**

In prior art, no published clathrate has been searched same as those of present invention formed from butylphthalide with cyclodextrin or its derivative. Therefor the clathrates of claim 1—5, and correspondingly, the processes to make them and their pharmaceutical use of claim 6—12 can satisfy the requirement of article 33.2 PCT .

**2) Inventive step**

Compared with butylphthalide, the clathrate of present invention is characterised by its favourable solubility in water and less vaso-stimulation, so it is more suitable to prepare solid and injection form. The claim 1—12 can satisfy the requirement of article 33.3 PCT .

**3) Industrial applicability**

Apparently, the the clathrate of present invention has the same medicinal property as butylphthalide, The claims can meet the requirement of article 33.4 PCT .